



AN ITALIAN COMPANY THAT RESEARCHES, DEVELOPS AND PRODUCES READY TO USE KITS
USING CHROMATOGRAPHIC TECHNIQUES FOR CLINICAL LABORATORIES

CONTROLS IN HAIR FOR ETHYLGLUCURONIDE – LEVELS 1 and 2

Code LC95019
TO USE WITH KIT CODE LC95010

OBJECTIVE

The controls in hair are used to calibrate the HPLC system for the quantitative measurement of analytes contained therein. Each analyte has a concentration that allows the construction of a calibration curve of six points.

STORAGE AND STABILITY

After opening the vial, withdrawn the necessary volume, closing it with the reagent used and keep a -25/-15 °C. Stable 6 months. Do not use it after the expiration date. **Reagent S – Blank hair** may be stored at ambient temperature while **Reagents Q1-Q2 – Chemical Standard Solution** must be stored at -25/-15°C.

PRECAUTIONS

These controls in human matrix should be treated with care and treated as potentially infectious.

LOT		

PACKAGING AVAILABLE:

- LC95019 CONTROL IN HAIR FOR ETHYLGLUCURONIDE- LEVELS 1 and 2
1 x 4000 mg/ 2 x 250 ul

N° 003	06/2024
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CONCENTRATIONS**CODE****LC95019**

		

STEP 1: Prepare 2 glass tubes of 10 ml call them L1-L2.

Add at each tube L1-L2 100 mg of **Reagent S** – Blank Hair (supplied in kit).

*NB: this phase corresponds to the **STEP 6** of ETHYLGLUCURONIDE in HAIR by LC-MS/MS methodology – Code LC95010.*

STEP 2: Add in each tubes 700 µl of **Reagent A** – Extraction Sol (**not included** in this packaging but in the kit Code LC95010)

*NB: this phase corresponds to the **STEP 8** of ETHYLGLUCURONIDE in HAIR by LC-MS/MS methodology – Code LC95010.*

STEP 3: Add in each tubes 20 µl of Reagent B diluted

(**not included** in this packaging but in the kit Code LC95010)

*NB: this phase corresponds to the **STEP 9** of ETHYLGLUCURONIDE in HAIR by LC-MS/MS methodology – Code LC95010.*

STEP 4: Add in each tubes of controls (L1-L2) the chemical standards **Reagents Q** as below:

Control L1	Control L2
20 µl of Reagent Q1	20 µl of Reagent Q2

At this point Controls of 2 points are ready and the concentrations to be used for the calibration curve will be:

Analyte	Control L1 (pg/mg)	Control L2 (pg/mg)
EtG	5,0	100,0
Range	4,0 – 6,0	85,0 – 115,0

Seal the tubes with the cap - Centrifuge for 3 minutes at 3500 rpm so as to submerge the hair in liquid

*NB: this phase corresponds to the **STEP 10** of ETHYLGLUCURONIDE in HAIR by LC-MS/MS methodology – Code LC95010.*

STEP 5: Incubate at 25 °C overnight

STEP 6 : Put in ultrasonic bath (sonicator) for 2 hours

Open the glass tubes

STEP 7 : Withdraw all the liquid being careful not to remove the hair and transfer in Eppendorf.

Centrifuge for 10 minutes at 14000 rpm

STEP 8 : Take the supernatant and put it in a glass vial.

INJECTION :

STEP 9 : Inject 12 µl of solution in LC system

* The procedures for production and validation / quality control of every batch shall be performed using the chromatographic method LC / MS / MS validated according to international guidelines of the Food and Drug Administration (FDA-May 2001) and the International Conference of Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH-Q2-R1-Nov 2005). The mean value and standard deviation were obtained during the validation phase of batch processing for level four bottles in duplicate.

This product fulfills all the requirements of Directive 98/79/EC of 27/10/1998 on in vitro diagnostic medical devices (IVD). The declaration of conformity is available upon request.



FOR IN VITRO DIAGNOSTIC USE ONLY



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